

Application Serial No. 10/639,076
Amendment dated April 13, 2005
Reply to Office Action of January 13, 2005

REMARKS

Entry of this Amendment and consideration of the comments presented herein is respectfully requested.

Claims 1-34 are pending in the application. Claims 1-18 and 27-31 were elected for prosecution. Claims 32-34 were added to the elected claims. Claims 19-26 are withdrawn until such time as a request for rejoinder may appropriately be lodged.

Applicants have cancelled claim 27 without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of this claim in one or more continuation applications.

Applicants have amended claims 1, 6, 12, 15, 18, 28, 32, 33, and 34. The claims have been amended to correct punctuation, and claim dependency. Applicants submit the amendments to the claims are supported throughout the specification and do not raise any issues of new matter.

Applicants have added new claims 35-43. Applicants submit that the newly presented claims are supported throughout the specification including at page 12, lines 33-37; and Figure 1-4.

Restriction Requirement and Election of Species

In response to the Restriction Requirement, Applicants elected the specie of SEQ ID NO:4. The Examiner contends that Applicants previously argued that SEQ ID NO.4 is a member of the genus related in chemical structure and function, and thus, is not patentably distinct. Applicants respectfully disagree with that characterization of the statements in response to the Restriction requirement. SEQ ID NO:4 is a specie of a claimed genus. Applicants did not argue that the species of the claimed genus are not patentably distinct, but that under 37 CFR § 1.141, that a reasonable number of species (independent and distinct though they may be) may be examined in one national application where there is an allowable generic claim. In addition, Applicants argued that it would not be unduly burdensome for the Examiner to search more than one species of the genus. Applicants did not state or argue in their response that the species were not patentably distinct. The Examiner's characterization of SEQ ID NO:4 as a member of the genus *comprising obvious variants* of the formula defined by claim 1 is an inaccurate characterization of Applicants remarks. Applicants did not state any such characterization but responded to the Examiner's indication that he was going to restrict the application to a single

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sequence by presenting arguments that the claims properly are genus and species claims. Applicants argued it would not be unduly burdensome to search additional species. Applicants assert that the species of the genus are patentably distinct from one another but that Applicant is entitled to a search of more than one species when the application includes an allowable generic claim. Applicants request that the Examiner clarify the record to indicate that Applicants have not at any time indicated that the species is a member of a genus comprising obvious variants of the formula of claim 1.

Double Patenting

The Examiner alleges that Claims 1-8 and 27-34 of this application conflict under MPEP § 822 with claims 2 and 4 of Application No. 10/356,257 under double patenting. Both applications are currently assigned to Genentech, Inc.

Applicants assert that a clear line of demarcation exists between Application 10/356,257, Lazarus et al., and the present application. Claim 2 of the 10/356,257 application is directed to a combination of a peptide from a genus similar to claim 1 of the present application and a peptide selected from the group of claim 1 of the 10/356,257 application. Claim 4 is directed to a pharmaceutical composition including claim 2. As such, claims 2 and 4 of the 10/356,257 application and claims 1-8 and 27-34 are directed to separate subject matter. Removal of the double patenting injections is respectfully requested.

35 U.S.C. § 102

Claims 1-17 are rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Slabas et al., U.S. Patent No. 5, 843,739. Applicants respectfully traverse.

The Examiner asserts that a search of the prior art produced 1,761,053 molecules encompassing the generic formula or claim 1; 251,389 molecules encompassing the generic formula or claim 15; 134,568 molecules encompassing the generic formula or claim 16; and 2424 molecules encompassing the generic formula or claim 17. Slabas et al. is asserted to teach one such molecule that encompasses the generic sequence defining claims 1, 2, 15-17. Specifically, the Examiner contends that SEQ ID NO:7 of Slabas et al. comprises the sequence LEU-ALA-VAL-VAL-LEU-SER-TRP-ALA-CYS-LEU-LEU that fits the generic formula of

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claims 1, 2, 15-17. The rejection further asserts that this sequence would inherently possess the ability to bind FVII as taught by the present claims. Applicants respectfully disagree with all of the above assertions.

Applicants thank the Examiner for the efforts in searching the claimed genus. The search was performed on STN CAS. Applicants note that the Examiner's search results for the specie of SEQ ID No:4 yielded only post-priority date publications. However, other searches for the broader geniuses do not accurately reflect the claimed subject matter.

Claim 1 is directed to a genus of peptides that may be described at least by a CYS residue separated from another CYS residue by 5 amino acids. Those positions are not substituted. In the searches with the numbers of results described above by the Examiner, those two positions were not required to be CYS. In the search performed, the residues at positions 5 and 11 were either allowed to be substituted by any amino acids or were omitted, thereby generating results that do not fit the claimed genus. The errant results include the portion of SEQ ID NO:7 of Slabas et al. identified by the Examiner. Please notice that SEQ ID NO:7 of Slabas et al. possesses one CYS residue but does not have a second CYS residue at a position five amino acids away from the other CYS residue.

For claims to be anticipated under 35 U.S.C. § 102, the reference must either explicitly or inherently teach all the limitations of the claim. In this case, the Slabas reference does not teach the two CYS residues required by the claims. In addition, there is no teaching in the Slabas et al. reference that would suggest that the sequence indicated by the Examiner would inherently possess the ability to bind factor FVIIa. Thus claim 1 and claims 2-17 dependent thereon are not anticipated by Slabas et al. Removal of the rejection is respectfully requested,

35 U.S.C. § 103

Claims 1-18 and 27-33 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Slabas et al. (U.S. Patent No. 5,843,739). Applicants respectfully traverse.

The rejection alleges that a search of the prior art produced 1,761,053 molecules encompassing the generic formula or claim 1; 251,389 molecules 251,389 molecules encompassing the generic formula or claim 15; 134,568 molecules encompassing the generic formula or claim 16; and 2424 molecules encompassing the generic formula or claim 17. The

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rejection additionally asserts that Slabas et al. teaches one such molecule that comprises the generic sequence defining claims 1, 2, 15-17. The Examiner also contends that SEQ ID NO:7 of Slabas comprises the sequence LEU-ALA-VAL-VAL-LEU-SER-TRP-ALA-CYS-LEU-LEU that fits the generic formula of claims 1, 2, 15-17. The rejection further asserts that the remainder of the claims are directed to obvious variants of SEQ ID NO:7 taught by Slabas et al., thus the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious. Applicants respectfully disagree with the above assertions.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met, namely: 1) the references when combined must teach or suggest all of the claim limitations; 2) a suggestion or motivation to, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the reference teachings; and 3) a reasonable expectation of success. Applicants submit that all of these requirements have not been met.

First, as described previously, Slabas et al. does not disclose all of the elements of Applicants claims. Claim 1 is directed to a genus of peptides that may be described at least by a CYS residue at position 5, and another CYS residue at position 11. Therefore, the assertion that a portion of SEQ ID NO:7 of Slabas et al. teaches a molecule encompassed by the generic formula of claims 1, 2, and 15-17 is not correct, because both Cys residues are not present in SEQ ID NO:7 of Slabas et al.. Second, Applicants respectfully disagree with the characterization that the peptides encompassed by the claims are obvious variants of SEQ ID NO:7 in Slabas et al. Slabas et al. is directed to DNA sequences encoding enzymes having membrane bound acyltransferase activity. Slabas et al provides no teaching related to factor VIIa much less the peptides of the present invention that bind to FVIIa. There is no teaching or motivation provided in Slabas et al. to develop the claimed peptides that bind FVIIa. Applicants respectfully assert that the claimed invention is non-obvious in view of the cited art. Withdrawal of the rejection is respectfully requested.

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Summary

Applicants submit that all pending claims are in condition for allowance, and notice to that effect is earnestly requested. The Examiner is invited to contact Applicants' representative at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,
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